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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,380	09/29/2000	Andre T. Baron	99-057	1919

7590 01/14/2003

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EXAMINER	
ANDRES, JANET L	
ART UNIT	PAPER NUMBER
1646	19

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/676,380	Applicant(s) BARON ET AL.	
	Examiner Janet L Andres	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *1-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 18 October 2002 is acknowledged. Claims 1-23 are pending in this application; claims 1-8 are withdrawn from consideration as being drawn to a non-elected invention. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

2. The objection to the specification is withdrawn in response to Applicant's amendment.

3. The rejection of claims 18-23 under 35 U.S.C. 103(a) is withdrawn in response to Applicant's argument that the art does not teach a decrease in receptor levels.

4. The rejection of claims 9 and 12-23 under 35 U.S.C. 112, first paragraph, as lacking enablement commensurate with the scope of the claims is withdrawn in response to Applicant's amendment.

Claim Rejections Maintained/New Grounds of Rejection

5. The rejection of claims 9-17 under 35 U.S.C. 103(a) is maintained for reasons of record in the office action of paper no. 14.

Applicant argues that the cited references teach that increased soluble receptor is associated with disease, whereas the instant specification teaches a decrease, and that this finding is not obvious. Applicant argues that the methods used by Partanen et al. and the '753 patent (U.S. patent 5674753, not 6674753, as was erroneously stated in the previous office action) give disparate results, and that the instantly claimed method has a greater dynamic range.

Applicant further argues that neither Graus-Porta nor Olayioye teach quantification and particularly do not teach quantification by sandwich-type immunoassay. Applicant additionally

argues that Johansen does not teach direct labeling of antibodies. Applicant concludes that, since the references do not teach Applicant's assay, it would not be obvious to combine them. Applicant further states that the cited references teach away from Applicant's invention, which teaches measurement of a decrease in soluble receptor.

Applicant's arguments have been fully considered but have not been found to be persuasive. Applicant's claims are to a method of quantifying a receptor, not to a method of diagnosis. What is claimed is an assay, not a method based on an unexpected finding resulting from the use of the assay. Thus, the unexpected finding of a decrease does not render the method unobvious; there is nothing in the claims that relies on such a decrease. That the '752 patent teaches disparate results does not argue that Applicant's assay is better: the cancer investigated in the '752 patent was breast cancer, not ovarian cancer and the results would not be expected to be the same. Similarly, Partanen et al. investigated asbestosis, not ovarian cancer. Further, neither of the references cited as indicating that Applicant's assay is superior provide a direct comparison between Applicant's assay at those used in the art; only comparisons to previously reported results are provide in, for example, table 2 of Baron et al., 2001. In addition, the higher levels reported by Baron et al. in that table are for the ALISA only and are thus relevant only to claims 16 and 17. Baron et al., 1998, similarly fails to provide a comparison of Applicant's assay with those known in the art, as would be required to show that Applicant's assay is in fact unexpectedly better. That the results are not directly comparable is explicitly taught by Baron et al., 1998, on p. 39, column 2, and p. 40, column 1. Further, as is the case with the 2001 paper, what was used was an ALISA and the teachings are thus relevant only to claims 16 and 17.

That neither Graus-Porta nor Olayioye teach quantification and that Johnson does not teach direct labeling with acridinium does not suffice to render the claimed invention unobvious. The level of skill in the antibody art is high; it would be *prima facie* obvious to one of ordinary skill to use any antibody shown to have appropriate binding specificity in a sandwich assay. Such assays are commonplace in the art. See, for example, examples 1, 4, and 5 of the '753 patent. Similarly, it would be obvious to directly label the antibody with acridinium, as stated in the office action of paper no. 14. The avidin/biotin system is a convenient method of detection, but directly labeled antibodies are wellknown in the art. See, for example, column 23, lines 20-23 and column 26, lines 25-29 of the '753 patent, in which a monoclonal was directly labeled with horseradish peroxidase or FITC, commonly used detection agents.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 9-23 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As amended, the claims are drawn to a method of detection of both soluble and full-length receptor, yet require the detection of the soluble receptor. Thus one of skill in the art would not be able to determine what was in fact to be detected.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 9-17 are rejected under 35 U.S.C. 102(a) as being anticipated by Baron et al., J. Immunol. Meth. 1998, vol. 219, pp. 23-43.

Since there are authors on this paper who are not named as inventors, the authors of the paper are considered to be "others"; see MPEP §2123(III). This paper, as Applicant indicates in the amendment filed 18 October 2002, discloses Applicant's assay and anticipates the limitations of claims 9 and 12-17. It further teaches that it can be used in serum and in body fluids in general (p. 29, column 2), thus anticipating the limitations of claims 10 and 11.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

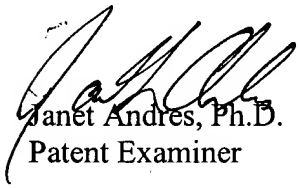
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that

sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Janet Andres, Ph.D.
Patent Examiner

January 10, 2003